## Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number is: K030452

MAR 0 3 2003

**Submitter's Name and Address**

Bayer Healthcare LLC
511 Benedict Avenue
Tarrytown, NY 10591
**Establishment Registration Number: 2432235**

Contact Person: Kenneth T. Edds, Ph.D.
Telephone: 914-524-2446
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**Contract Manufacturer**

Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA 92618
Establishment Registration: 2016706
Owner Operator Number: 9929003

| | |
|---|---|
| **Device Name**: | Ligand Plus 1,2,3 Controls |
| **Proprietary/Trade Name** | Bayer Ligand Plus 1,2,3 |
| **Common Name**: | Quality Control Material |
| **Classification Name**: | Enzyme Controls (assayed and unassayed) |
| **Classification**: | Class I |
| **Regulation Number**: | 21 CFR 862.1660 |
| **Panel**: | Chemistry (75) |
| **Product Code**: | JJY |

**Predicate Device:**

Ligand Plus 1,2,3 Controls
Premarket Notification Number: K901212

**Device Description:**

The Ligand Plus 1, 2, 3 Controls are three separate levels of quality control material prepared from human serum with non-serum constituents added. The analytes currently in the control material are:

Alphafetoprotein
CEA
Cortisol
Estradiol
Ferritin
Folic Acid
FSH
HCG
IgE
LH
Progesterone
Prolactin
PSA
T3
T3-free
T4
T4-free
Testosterone
Thyroid Uptake
TSH
TSH-3
Vitamin B12
Carbamazepine
Digoxin
Gentamicin
Phenobarbital
Phenytoin
Theophylline
Tobramycin
Valproic Acid
Vancomycin

The intention of this submission is to add the following three constituents to the existing control:
Intact PTH (iPTH, or intact parathyroid hormone)
Insulin
c-Peptide

**Intended Use:**

The Ligand Plus 1, 2, and 3 controls are assayed control materials for in vitro diagnostic use to monitor the precision and accuracy of immunochemistry test procedures for the ADVIA Centaur® andACS:180® Systems.

**Substantial Equivalence**:

The Ligand Plus 1, 2, and 3 controls are identical in intended use, storage and handling, stability, source material (human serum), and instructions for use as the previously cleared Ligand Plus 1, 2, 3 Controls. The only difference in these controls is the addition of three new analytes: iPTH, Insulin, and c-Peptide.

As with the predicate device, the control material is lyophilized and requires reconstitution with 5.0 mL reagent grade water. These controls are only for use on the Bayer ADVIA Centaur and ACS:180 Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 0 3 2003

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k030452
Trade/Device Name: Ligand Plus 1, 2, 3 Controls
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: February 6, 2003
Received: February 11, 2003

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030452

Device Name: Ligand Plus1, 2, 3

**Indications for Use:**

Assayed control material for in vitro diagnostic use to monitor the precision and accuracy of immunochemistry test procedures for the ADVIA Centaur® andACS:180® Systems.

(PLEASE DO NOT WRITE ELOW THIS LINE—CONTINUE ON ANOTHER PAGE, IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030452